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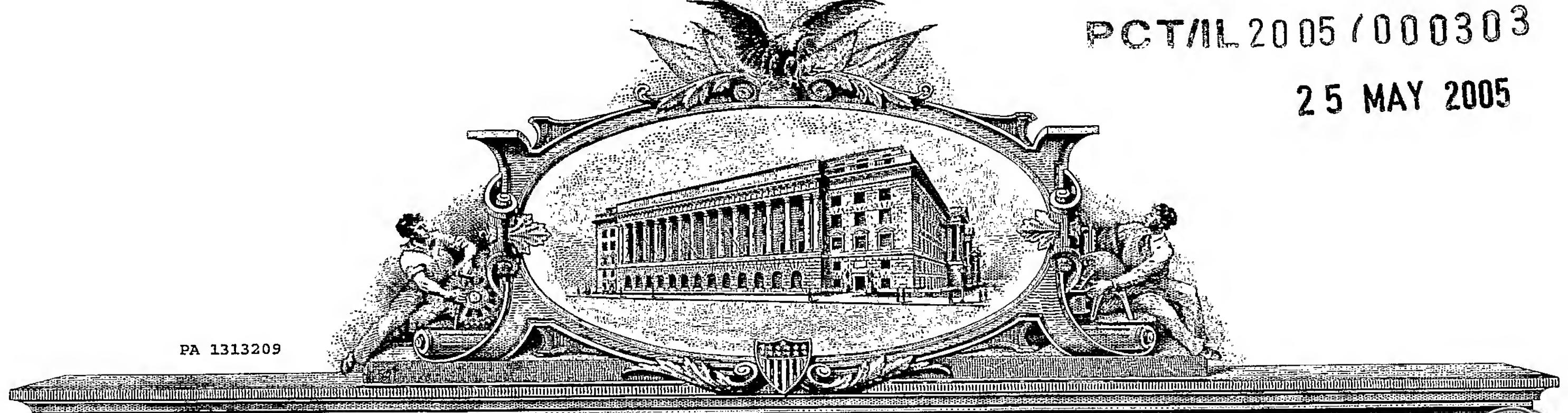
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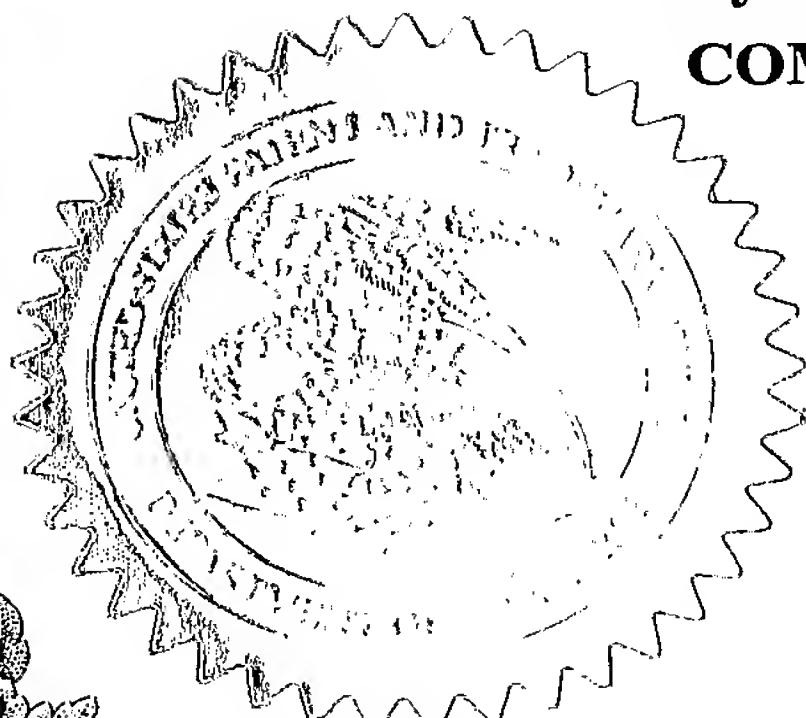
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APPLICATION NUMBER: 60/553,965

FILING DATE: March 18, 2004

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INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
ELAN	ZIV MD	RAMAT GAN, ISRAEL

Additional inventors are being named on the _____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

**A DISPOSABLE DEVICE FOR TREATMENT & PREVENTION OF DELMIC
ORGAN PRELAPSE**

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<input type="checkbox"/> Firm or Individual Name	ELAN ZIV MD		
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ENCLOSED APPLICATION PARTS (check all that apply)

<input checked="" type="checkbox"/> Specification Number of Pages	8	<input type="checkbox"/> CD(s), Number _____
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets	5	<input type="checkbox"/> Other (specify) _____
<input checked="" type="checkbox"/> Application Data Sheet. See 37 CFR 1.76		

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<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.	FILING FEE Amount (\$)
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

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[Page 1 of 2]

Respectfully submitted,

SIGNATURE DR. E. ZIV MDTYPED or PRINTED NAME DR. E. ZIV MDTELEPHONE +972-53-569928Date 15.3.04REGISTRATION NO. _____
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1321
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Effective 10/01/2003. Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 80)

Complete if Known

Application Number		
Filing Date	MARCH 15, 2004	
First Named Inventor	Dr Elan Ziv	
Examiner Name		
Art Unit		
Attorney Docket No.		

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Large Entity	Small Entity	Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1001 770	2001 385	Utility filing fee			
1002 340	2002 170	Design filing fee			
1003 530	2003 265	Plant filing fee			
1004 770	2004 385	Reissue filing fee			
1005 160	2005 80	Provisional filing fee	80		
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2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

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		-20** =		
		- 3** =		

Large Entity	Small Entity	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 86	2201 43	Independent claims in excess of 3
1203 290	2203 145	Multiple dependent claim, if not paid
1204 86	2204 43	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent
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FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity	Small Entity	Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath			
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet			
1053 130	1053 130	Non-English specification			
1812 2,520	1812 2,520	For filing a request for ex parte reexamination			
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action			
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action			
1251 110	2251 55	Extension for reply within first month			
1252 420	2252 210	Extension for reply within second month			
1253 950	2253 475	Extension for reply within third month			
1254 1,480	2254 740	Extension for reply within fourth month			
1255 2,010	2255 1,005	Extension for reply within fifth month			
1401 330	2401 165	Notice of Appeal			
1402 330	2402 165	Filing a brief in support of an appeal			
1403 290	2403 145	Request for oral hearing			
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1808 180	1808 180	Submission of Information Disclosure Stmt			
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1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))			
1801 770	2801 385	Request for Continued Examination (RCE)			
1802 900	1802 900	Request for expedited examination of a design application			

Other fee (specify)

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Signature			March 14, 2004

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A DISPOSABLE DEVICE FOR TREATMENT & PREVENTION OF PELVIC ORGAN PROLAPSE.

The present invention relates generally to the field of treatment and prevention of pelvic organ prolapse in female patients. The invention describes a vaginal disposable device which is inserted and removed in a no-self-touch technique, by the patient herself, using a disposable applicator.

10 Inventor: Dr Elan Ziv, MD OBGYN, Urogynecologist

Background of the Invention

General Data

Definition

15 Pelvic organ prolapse is defined as a condition in which vaginal wall support is lost, and various pelvic organs prolapse into the vagina. This is a very bothering condition, though in most cases it is not a dangerous one. It might appear alone or in combination with urinary stress incontinence.

20 POP (Pelvic Organ Prolapse) is a very common condition in females, in which various organs, surrounding the vagina, prolapse into it. The reasons for such prolapse are numerous, mainly because the vagina has a very low tensile strength within its walls due to damage to muscles, nerves, fascias etc. There might also be a change within the collagen content, thereby causing a weaker pelvic floor. According to the older definition, prolapse may be divided into five categories, according to the organ that is **25** sagging down (urethra, bladder, uterus, rectum and the pouch of Douglas (small bowl)), and to three grades according to the amount of descent (within the vagina, at the entrance to the vagina, protruding out of the vagina). There might be a combination of various organs prolapse at the same time, with different level of descent. The newer classification (POP-Q) takes into account other factors, such as location of the prolapse **30** and the distance from the entrance of the vagina. There is very little data regarding the prevalence of the problem but it seems to be age related, and older women have much higher tendency towards developing some form of pelvic organ prolapse.

High risk group for Pelvic Organ Prolapse

There are very few statistical & Epidemiological studies regarding the causes for the development of pelvic organ prolapse and high risk groups. The main risk factors are:

- Advanced age
- Pregnancy
- Delivery. During labor, there are many tears, stretchings and hematomas within the muscles, the ligaments and the nerves of the pelvic floor. Instrumental delivery might be a further factor.
- Number of deliveries
- Race. White women tend to have more prolapses than black or oriental women.
- Menopause
- Obesity
- Hard labor.

15 Prevalence

It was found that the prevalence of severe pelvic organ prolapse in women with jobs in labor/factory positions was 11.1%, 6.6% among those working at home, 3.0% in professional/ managerial jobs, 3.3% in service, and 0.8% among technical/sales/clerical workers. Laborers/factory workers had significantly more severe prolapse than the other job categories ($P < .001$). Table 1 summarizes some article on the subject

APPENDIX 1 – Prevalence Rates of POP

	Samuelsson et al 1999 Sweden	Bland et al 1999 U.S.	Progetto Menopausa 2000 Italy	Swift 2000 U.S.
N	487	241	21,449	497
Age range	20-59	45-55	Around menopause 1	8 - >70
Race				
White	100%	89%	100%	47%
Black		9%		52%
Parous	54%	Unspecified	85.6%	93%
Hysterectomy	4%	28%	None	26%
Staging technique	Above, i.e. beyond hymen	ICS	Uterus only Baden 0, 1, 2, 2	ICS
Stage				
0	71.2%	73%	94.5%	6.4%
1	28.8%	23%	3.6%	43.3%
2	2%	4%	1.9%	47.7%
3	0	0		2.6%
4	0	0		0
Source of subjects	76% of every 3 year screen participants	Responded to ad for soybean supplement study	268 first-level menopause clinics in Italy.	Routine gynecolo- gic examination

TABLE 1

"A disposable device for treatment & prevention of pelvic organ prolapse"
Dr Elan Ziv, MD OBGYN, Urogynecologist

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Anatomy and pathophysiology

Understanding the female genital anatomy is extremely important in order to understand the basis of this invention.

FIG. 1A is an anatomical frontal cut section of the vagina

5 FIG. 1B is a front view of vagina creating the shape of the letter H.

FIG. 1C is a side view of the vaginal diameters.

FIG. 2 is a side view of the female pelvis.

The vagina is a hollow organ with multiple shapes and diameters at different depths.

10 The sidewalls (FIG.1A) have thin longitudinal and circular muscles (8), externally wrapped by the pelvic fascia (10), which tends to become weakened, stretched and attenuated over the years and allow for sagging and prolapse of different pelvic organs into and through the vagina. Internally the vagina is covered with the mucosa (6).

15 Although potentially being a tube, the vaginal cavity is almost always obliterated with the anterior wall (12) and the heavy bladder on it collapse and fall into the vaginal lumen. The posterior wall is pushed anteriorly by the bowel (14), thereby creating the shape of the letter H (FIG.1B). Vaginal diameters, either lateral or antero-posterior (FIG.1C, FIG.2) are never the same along vaginal axis. Lateral diameter is usually shorter closer to the entrance (18) gradually becoming longer internally (16). The same 20 applies for the antero-posterior diameter, while diameter close to the entrance (44) is usually shorter than the one behind the perineal body (48). The vagina may therefore be looked at as a funneled shape organ.

There are certain defined organs in direct contact with the vagina or within short proximity. The bladder (36) is a hollow, sack like organ, in which the urine is 25 accumulated prior to it's expulsion outside the body through the urethra (42). The bladder is located behind the pubic bone (38) and rests on the middle third of the vagina. The urethra is a short muscular pipe, 25-35 mms in length, in direct contact with the bladder at the bladder neck (40) resting on the lower third of the anterior vaginal wall, in direct contact with the pubic bone. The uterus (30) is a pear shaped organ that 30 has a lower part, the cervix (32) which protrudes into the dome of the vagina. The body of uterus is an abdominal organ, which, in most cases bands forward on the bladder. The cervix, while protruding into the vagina creates 4 fornices – 2 laterals which are of the same dimensions, one smaller anterior (34), and one posterior (22), which is actually

behind the cervix. The posterior fornix has direct contact with the pouch of Douglas (20) which is the deepest part of the abdominal cavity, on top of the vagina. The posterior surface of the vagina is in contact with the rectum (24), until the area where a thick muscular body, the perineal body (26) which is part of the pelvic floor and the 5 sphincter of the anus (28).

Prolapse of adjacent organs into the vagina is quite common, in variable degrees. The reasons for such a prolapse are mainly damage to the endopelvic fascia which surrounds the organs and keeps them in the right position, pelvic floor muscular damage, and 10 neural damage. Prolapse of the urethra, named urethrocel, is one of the several possibilities for pelvic organ prolapse around the vagina. The most frequent prolapse is of the bladder, named cystocele, as a result of its weight. Prolapse of posterior fornix, with bowel inside is called enterocele, and prolapse of the posterior vaginal wall with the rectum in it is termed rectocele. When the ligaments that hold the uterus in place 15 weaken, a uterine descent occurs. In cases where the uterus has been removed, and the vagina is dome shaped, a vault prolapse may occur.

Current treatment

At present – there are 2 ways of dealing with Pelvic Organ Prolapses:

20 1. Surgical – vaginal or abdominal
2. Use of vaginal devices (pessaries) that are inserted into the vagina and mechanically reduce the prolapse by pushing the wall aside and upwards.

Efforts to avoid surgical procedures have resulted in the development of a number of non-surgical vaginal devices, inserted into the vagina by the surgeon or the patient.

25 Vaginal devices are well known for their tremendous diversity in shapes and sizes. These devices are meant to prevent prolapse of the vaginal walls, with different location of pressure application.

Some of these devices tend to block all flow of urine from the bladder. Therefore, when 30 a patient needs to urinate, the device must be removed from the vagina or must be collapsed to remove the pressure applied against the bladder neck. Trying to solve this problem, vaginal devices were developed in special shapes, without completely blocking the bladder neck so that the patient may urinate with the device in place (for example, US patents 6189535 B1, 6158435, 5894842, 5611768). These devices,

however, are generally large and intrusive and, therefore, are uncomfortable to wear, with low patient satisfaction and compliance. They are also relatively expensive, and therefore designed to be reusable.

5 There are several drawbacks of existing vaginal devices:

1. Most of them are intended to be reusable, hence they are made as resilient large bodies, made of plastic, hard rubber, or other such materials, in order to preserve their shape and function for a long time.
2. Insertion of large noncompliant bodies is sometimes difficult, painful or 10 unpleasant, sometimes necessitating a medical practitioner. Removal causes same unpleasantness.
3. Most reusable devices are meant to remain in the vagina for prolonged periods of time, thereby causing irritations, pressure ulcers, infections, foul smelling discharge, etc.
4. Such reusable devices have a long standing bad reputation among patients and medical practitioners for being unpleasant, causing infectious discharge and foul odor, and being associated with disability and old age.
5. Some reusable devices are meant to be inserted daily by the patient, and to be removed after several hours, by means of pulling a string or with a finger, to be cleaned for re-use, and to be kept in certain conditions prior to following insertion. Some patients are reluctant to touch their selves in such intimate parts 20 of their bodies, or disgusted to clean the device, hence their reluctance to use it.

Vaginal devices may cause three main side effects:

1. **Infections**-any foreign material, anywhere in the body, may become infected by several kinds of organisms, and cause formation of a foul smelly discharge. Reusable devices are certainly prone to cause such infections, but also, less frequently, disposable ones. In order to prevent such infections, devices should be:
 - 30 • disposable
 - used for a limited length of time, in order to prevent organism from growing, and to prevent damage, by vascular pressure, to the vaginal wall.

- made in a way that will allow vaginal or cervical normal secretions to flow out of the body
- made of certain known materials that would not permit growth of organisms.

5 2. **Toxic Shock Syndrome (TSS)** is a condition, described some years ago, in which abundant growth of *Staphylococcus Aureus*, a bacteria that utilizes the cellulose within sanitary menstrual tampons, released large amounts of toxin. That toxin caused a collapse of vital body systems, forming a dangerous condition. In order to overcome this, sanitary tampons do not contain cellulose anymore, and vaginal devices, as described earlier, should be made of materials that would not permit the growth of bacteria, and allow for discharge flow. This is best done by using properly made disposable devices.

10 3. **Pressure Necrosis** – prolonged pressure on the vaginal sidewalls may cause pressure on blood vessels with resultant necrosis, bleeding and infections. This might be prevented by using disposable devices only, for a predetermined length of time.

15

20

The invention

FIG. 2 is a side view of the female pelvis.

FIG. 3A is a top view of the invention.

FIG. 3B is a side view of the invention.

5 FIG. 4 is a perspective view of the applicator.

FIG.5A is a sectional side view of the device within the applicator.

FIG.5B is a sectional top view of the device within the applicator.

The device (FIG. 3) is intended to be applied into the vagina with an applicator much
10 like the insertion of a regular menstrual tampon .After insertion, the device should
expand significantly to the predefined shape and size, thereby exerting predefined
appropriate pressure on both lateral vaginal walls, pushing them aside. The apex of the
vagina shall be pushed upwards at the same time. That expansion of the device shall
eventually create linear stretching of the anterior & posterior vaginal walls, while
15 creating a new shape of intra-vaginal hollow (rectangle). The device may be left inside
the vagina for several hours. Removal for disposal will occur while pulling a string and
collapsing the device to a much smaller size.

The device (FIG. 3A), from a top view, looks like a round ring (50+52) and a string
20 (54). It is made of elastic materials, such as silicon, polyurethane, etc. This flexible
material gives the device the ability to be folded into the applicator, and to be pushed
out easily in small dimensions into the vagina. The device is covered by a sponge
rubber (52) which makes it more comfortable to wear. The sponge is also reducing the
pressure on the vagina's sidewalls and helps preventing pressure necrosis. FIG.3B is a
side view of the ring what shows its convex shape. This unique shape helps the ring to
25 be folded and inserted easily into the applicator.

As with an ordinary menstrual tampon, (FIG.4) the device will be kept and supplied
within an applicator, ready for use. FIG.5A is a sectional side view of the device (56)
inside the applicator (58). FIG.5B is a sectional top view of the device (60) inside the
applicator (62).

30 Removal of the device is inherited within the device itself. Pulling the string (54), which
will protrude outside of the vagina as with the regular menstrual tampon, will cause the
device to reduce in size and be pulled out of the vagina by the same pull of the string, in
order to be wasted.

Discharge will be allowed to flow out of the vagina, as due to its shape, the device does not block the vagina.

The device is intended for use in women who suffer from a prolapse of at least one of the above mentioned organs. Preferably, it should aim at women who suffer from any 5 prolapse descending as low as the level of the hymen, but it might just as well be used in women who have greater degrees of prolapse

The invention has in its basic concept the following features:

- Being a disposable device.
- 10 • Insertion of the device is always with an applicator.
- Easy & comfortable insertion and removal.
- Being comfortable to wear.
- Being hygiene & odorless
- 15 • Being a familiar procedure to most female patients – as inserting a menstrual tampon.
- Being inserted by the patient herself, in a no-self-touch technique, with a disposable inserter.
- Being removed by the patient herself, in a no-self-touch technique, with the device collapsing and becoming of small size for painless removal.
- 20 • Being of high availability, easy to get everywhere, sold as an Over the Counter (OTC) device.
- Being of low cost.
- Having complete confidentiality, as with the use of menstrual tampons.
- Having the ability to be removed instantly when needed.
- 25 • No blockage of vaginal discharge.

Alternative embodiments of the invention.

- It may be manufactured in different sizes
- 30 • It may be made of many flexible materials, such as plastics, cardboard, etc.

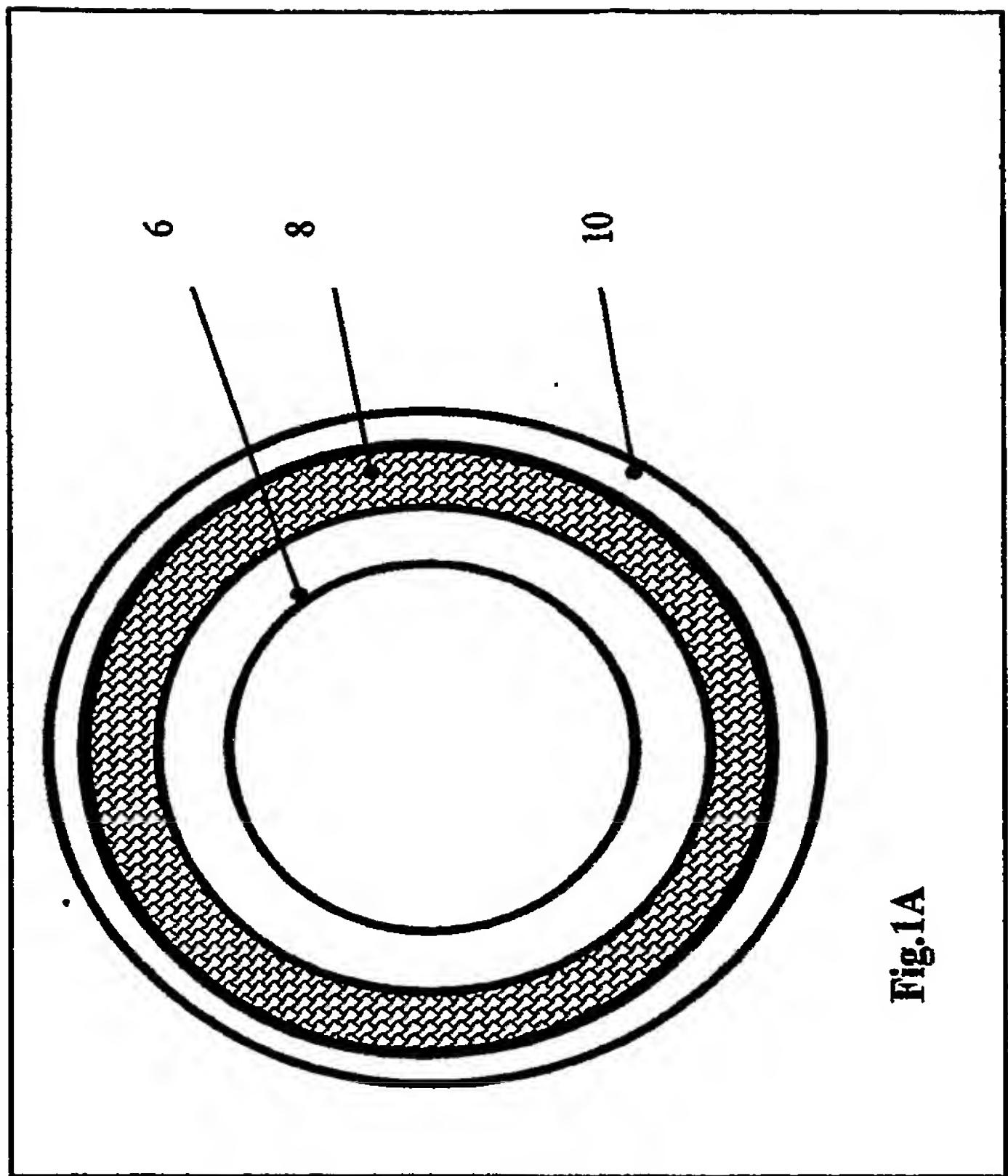


Fig.1A

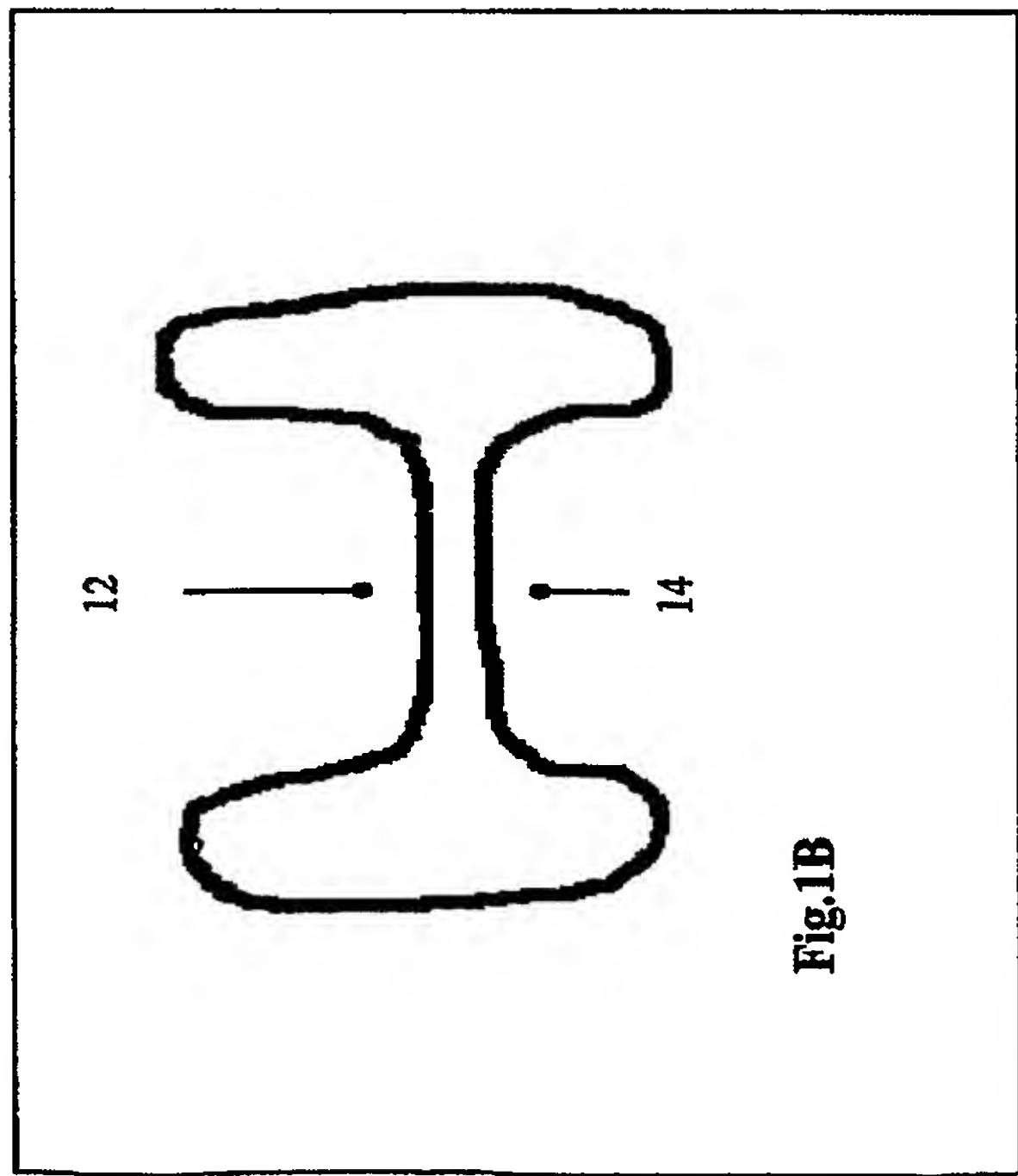


Fig.1B

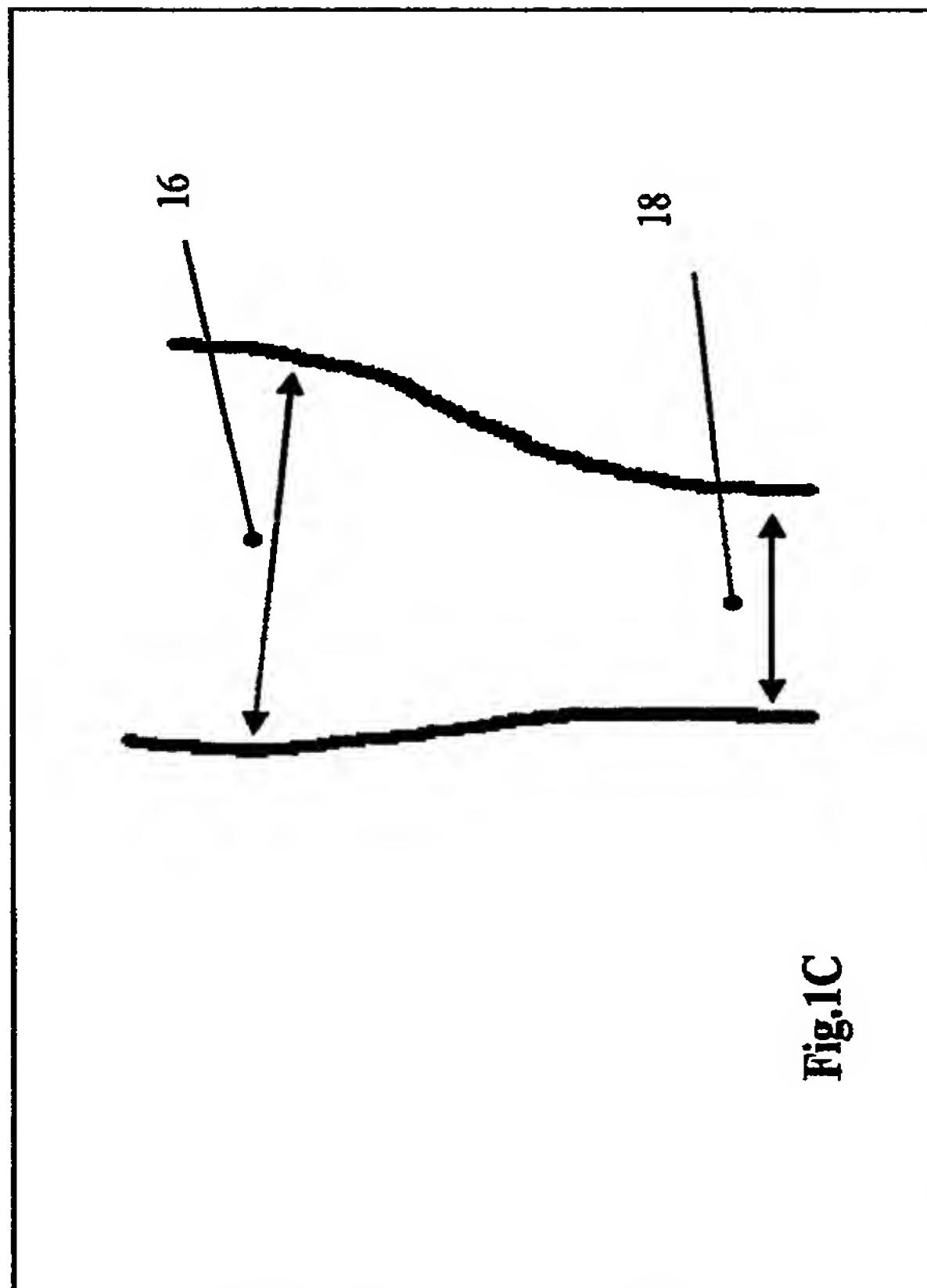


Fig.1C

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"A disposable device for treatment & prevention of pelvic organ prolapse"
Dr Elan Ziv, MD OBGYN, Urogynecologist

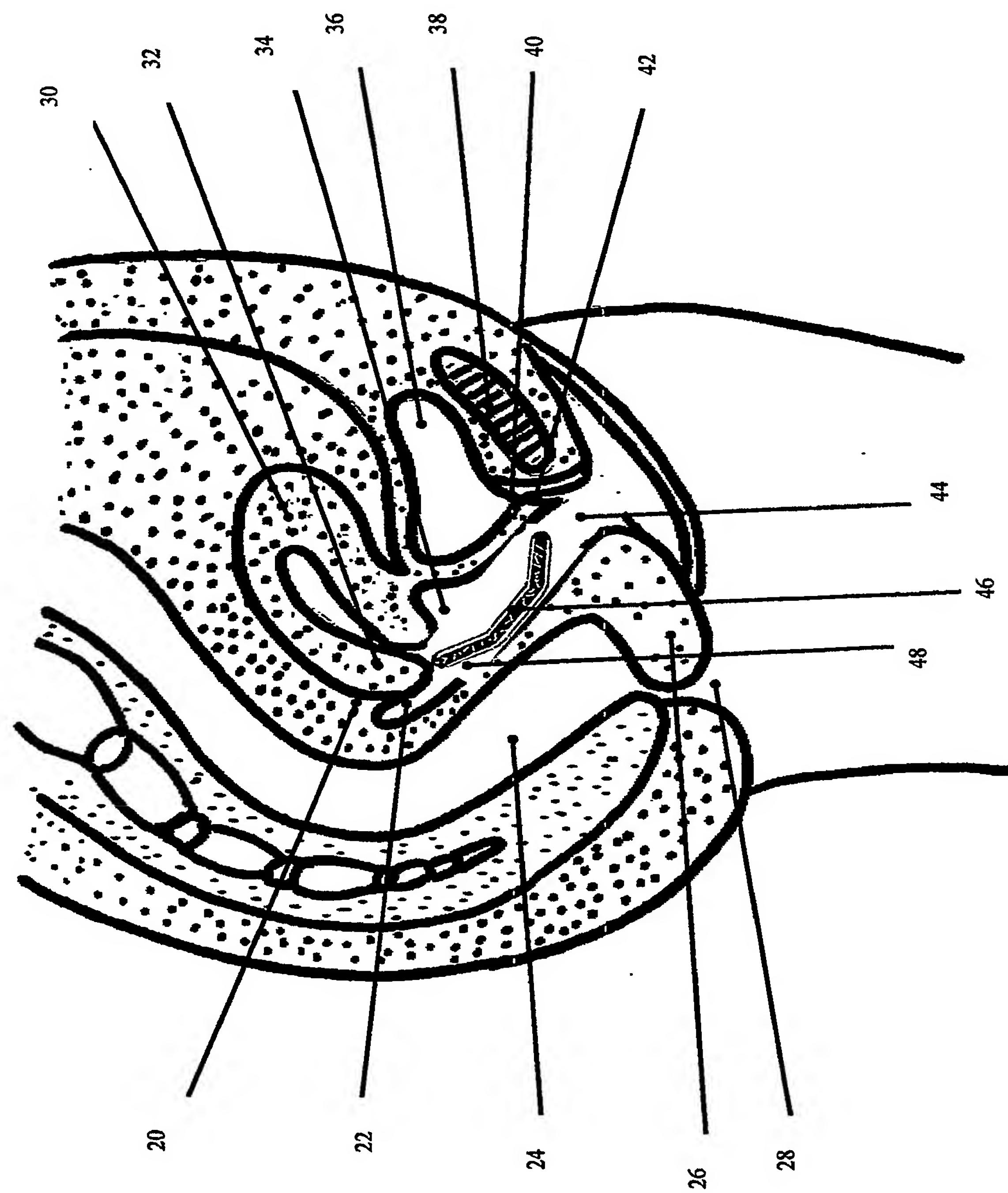


Fig.2

"A disposable device for treatment & prevention of pelvic organ prolapse"
Dr Elan Ziv, MD OBGYN, Urogynecologist

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"A disposable device for treatment & prevention of pelvic organ prolapse"

Dr Elan Ziv, MD OBGYN, Urogynecologist

Fig.3B

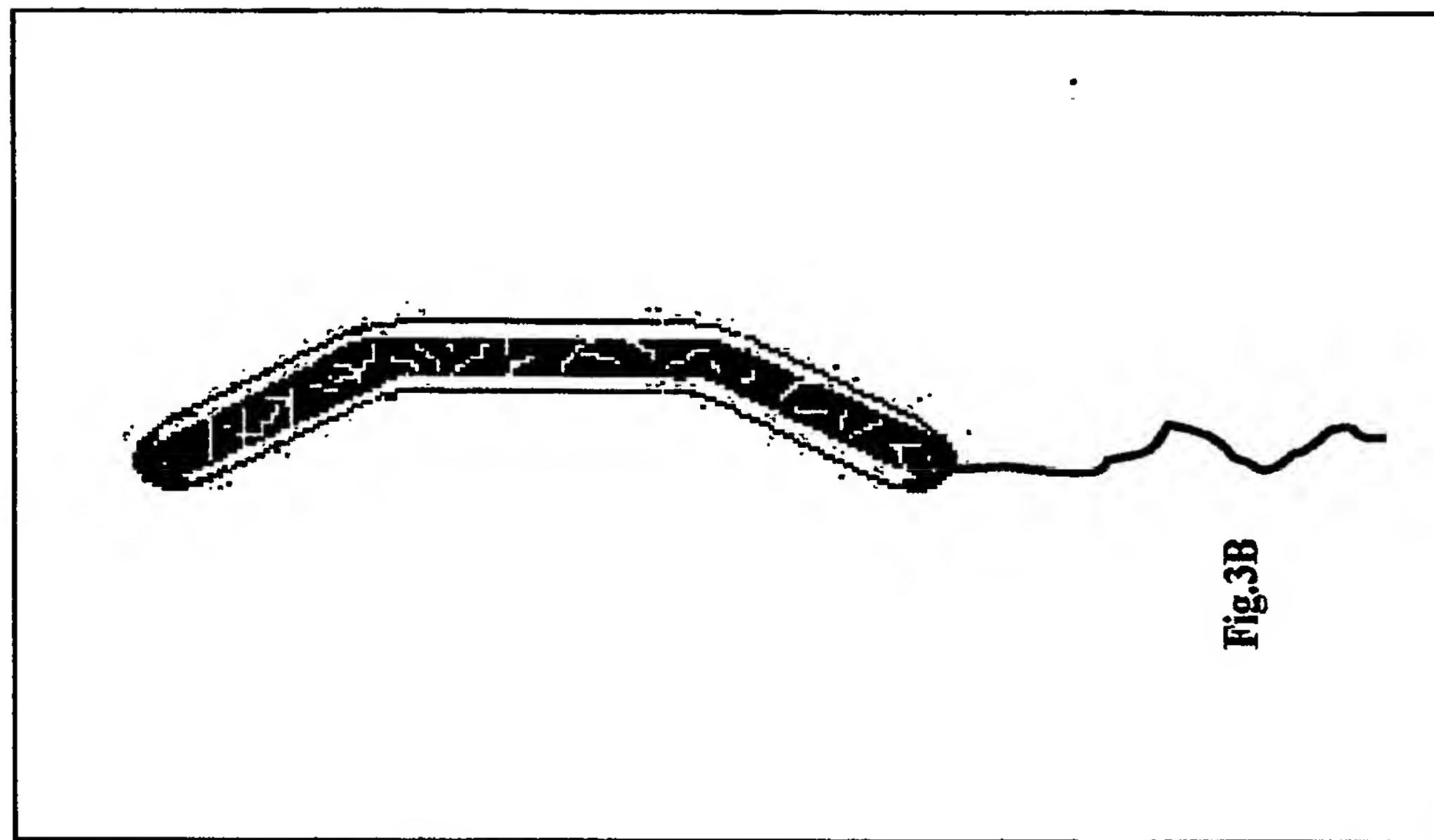
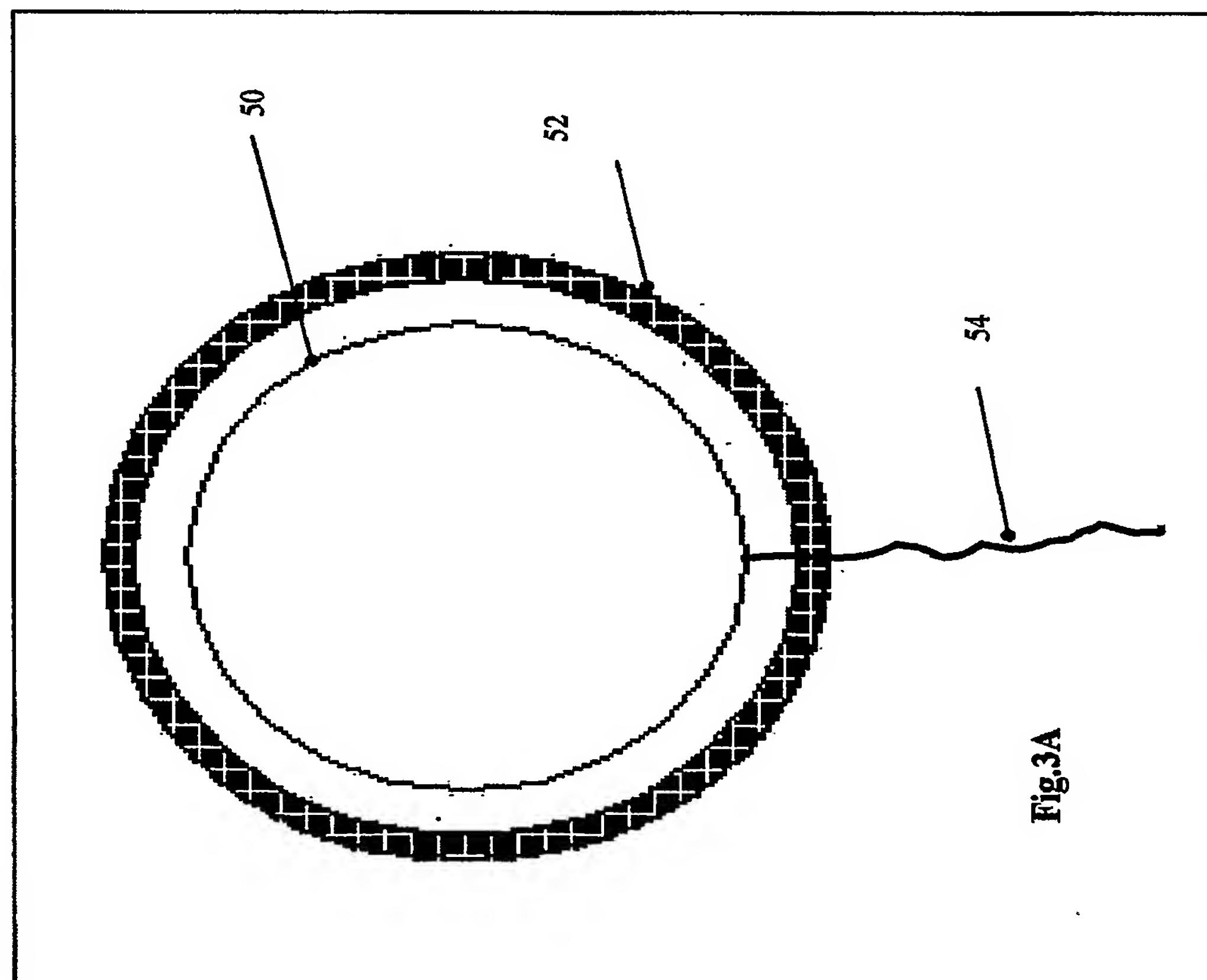
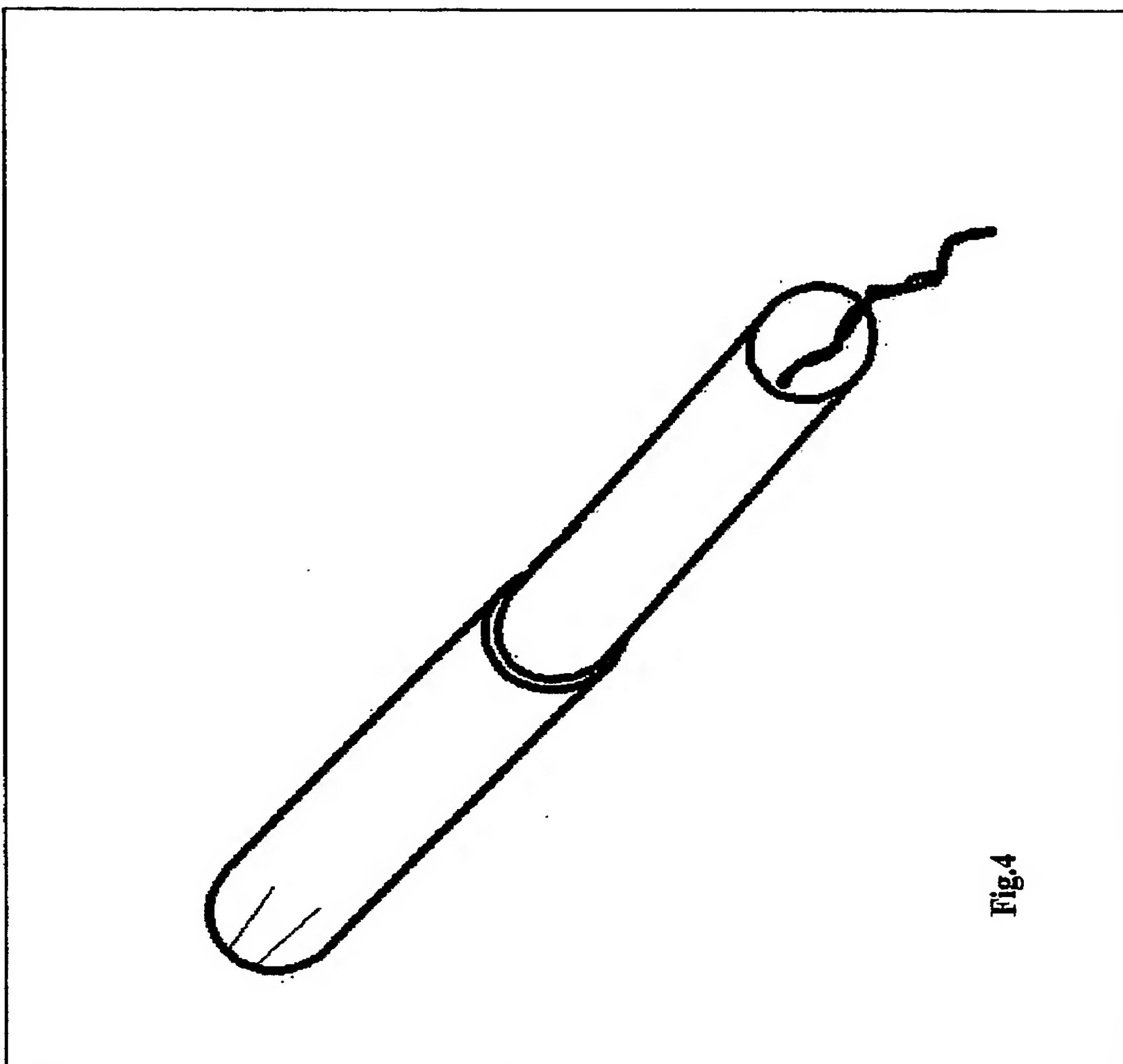


Fig.3A



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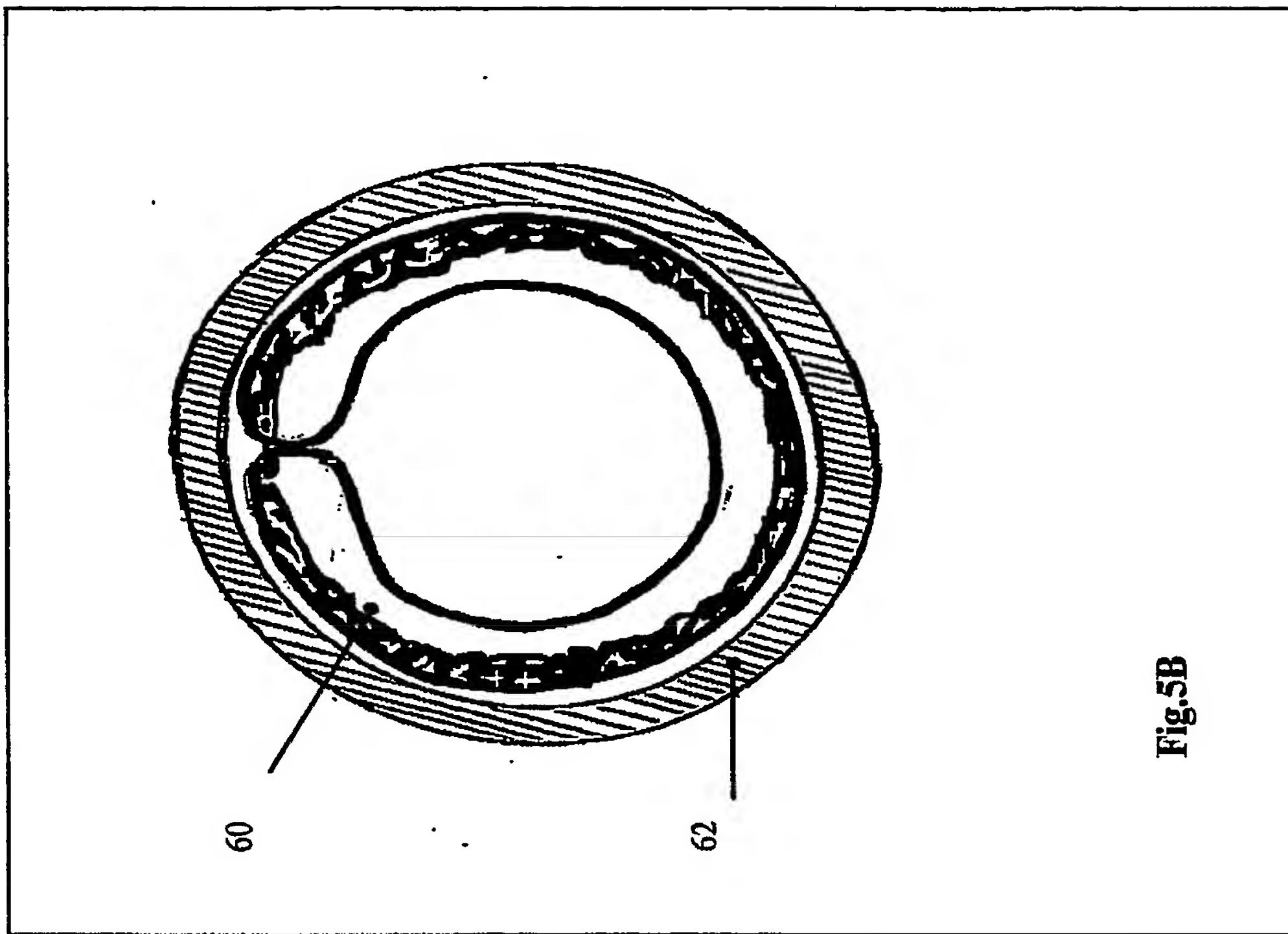


Fig.5B

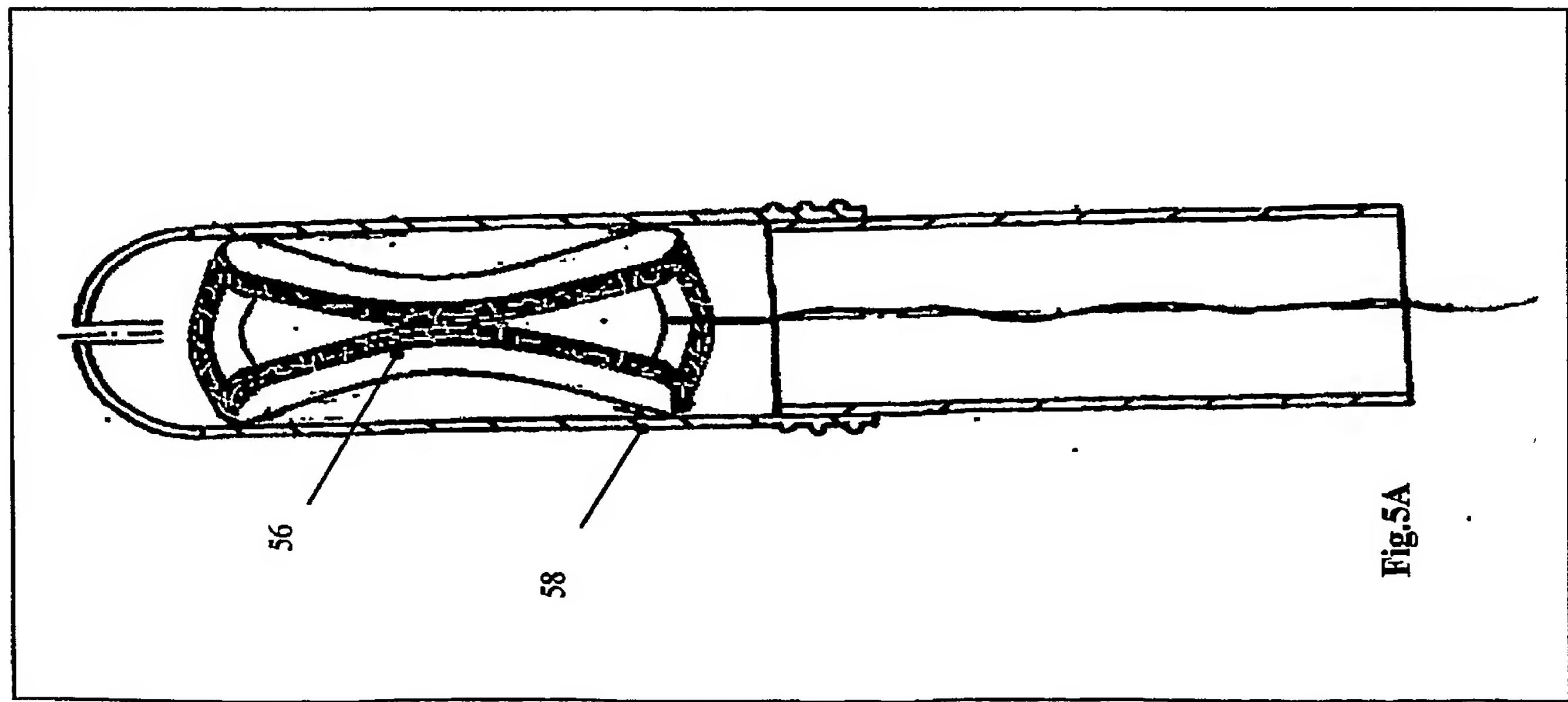


Fig.5A

"A disposable device for treatment & prevention of pelvic organ prolapse"
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